

**REMARKS****1. Preliminary Remarks****a. Status of the Claims**

Claim 23, 25, 31, 33, 39, and 40 are pending in this application. Claims 31, 33, 39 and 40 are amended. Claim 25 is allowed. Applicant respectfully request entry of the amendments and remarks made herein into the file history of the application. Upon entry of the amendments, claims 23, 25, 31, 33, 39 and 40 will be pending and under active consideration.

**b. Amendment to the Claims**

In order to expedite prosecution and without prejudice to seeking claims of a broader scope in a continuing application, claims 31, 33, 39 and 40 have been amended to be directed to a vector or probe comprising a human insert, wherein the human insert consists of the sequence of the nucleic acid of claims 23 or 25 and where the vector/probe comprise no other insert but the nucleic acid of claim 23 or 25.

**c. Amendment to the Specification**

On pages 2 and 3 of the Office Action, the Examiner asserts that the application contains disclosure entirely outside the bounds of the allowed claims. The Examiner further asserts that the Applicant is required to modify the brief Summary of the Invention as well as amend the specification to include all descriptive matter pertinent to SEQ ID NOS: 348 and 4233864. The Examiner further requests that the additional disclosure of Tables 1-11 that do not relate to SEQ ID NOS: 348 and 4233864 be removed.

In response, Applicant will be submitting amendments to the specification to be in harmony with the claimed invention as well as incorporate the relevant information from Tables 1-11 regarding SEQ ID NOS: 348 and 4233864 while deleting the remaining material. Due to the size of the tables and number of amendments to be made, Applicant will be providing these amendments in a supplemental response.

**d. Claim Objections**

On page 3 of the Office Action, the Examiner objects to claims 33 and 40 for typographical errors regarding the word heterologous. In view of the foregoing amendments, the objection is moot because the word "heterologous" or its misspelled counterparts has been deleted from the claims. Accordingly, Applicant request withdrawal of the objection.

## 2. Patentability Remarks

### a. 35 U.S.C. §102(b)

On pages 3-5 of the Office Action, the Examiner rejects claims 31 and 39 under 35 U.S.C. §102(b) as being anticipated by Dunn et al., GenBank Accession No. AZ593982 (hereafter “Dunn”), and alternatively, claims 31, 33 and 40 under 35 U.S.C. §102(b) as being anticipated by Birren et al., GenBank Accession No. AC015918 (hereafter “BAC clone”). In view of the foregoing amendments, Applicant respectfully disagrees.

Specifically, the phrase “human insert consists of the nucleic acid of claims 23 and 25” is supported in paragraph 0035 for the vectors and the probes in the specification. Specifically, paragraph 0035 states “the vectors comprise the DNAs” and “the probes comprise the DNAs.”<sup>1</sup> The DNAs are nucleic acid comprising the claimed nucleic acids of claims 23 and 25. These sequences are human sequences and importantly, the vector and probe claims comprise no other inserts other than the nucleic acids of claims 23 and 25. The vector of Dunn contains an insert that is 701 nucleotides and the BAC clone is 220,581 nucleotides in length. Thus, the Dunn insert and the BAC clone insert are far longer than the inserts required in the vector or probe claims 31, 33, 39 or 40, and therefore do not meet the claimed length limitations. Furthermore, none of the cited §102 references teach or suggest any insert except for the Dunn insert of 701 nucleotides or the BAC clone of 220, 581 nucleotides. In view of the foregoing amendment and remarks, the Applicant respectfully submits that the rejection of claims 31, 33, 39 and 40 under 35 U.S.C. §102(b) over Dunn or the BAC clone has been overcome and requests that the rejection be withdrawn.

### b. 35 U.S.C. §103(a)

On pages 7 and 8 of the Office Action, the Examiner rejects claims 23 and 39 under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 7,250,289 (hereafter “Zhou”). Specifically, the Examiner asserts that Zhou discloses an array probe (SEQ ID NO: 669995) that is at least 80% identical/complementary to SEQ ID NO: 348 and its complements. The Examiner further alleges that Zhou teaches that its’ nucleic acids may range from 2 to at least 8, 15 or 20 nucleotides in length or from 1 to 1000 monomers. The Examiner asserts that one of skill would envision nucleic acid probes of 8 to 25 nucleotides and would be motivated to make a 23 or 24-mer equivalent to SEQ

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<sup>1</sup> [0035] Accordingly, the invention provides several substantially pure nucleic acids (e.g., genomic DNA, cDNA or synthetic DNA) each comprising a novel GAM oligonucleotide, vectors comprising the DNAs, probes comprising the DNAs, a method and system for selectively modulating translation of known target genes utilizing the vectors, and a method and system utilizing the GAM probes to modulate expression of GAM target genes.

ID NO: 669995, which therefore include sequences at least 80% identical/complementary of SEQ ID NO: 348 and complements thereof. Applicant respectfully disagrees.

With regard to a sequence at least 80% identical to SEQ ID NO: 348, wherein the sequence is 19-24 nucleotides in length, or complements thereof, Applicant submits that even if the primer cited by the Examiner includes these variants or complements thereof, this is not sufficient by itself to establish a *prima facie* case of obviousness. See MPEP §2144.08.II (“The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness”). Zhou teaches 982,914 mouse related sequences and variants/complements thereof that can range in size from 1 to 1000 monomers and none of these sequences are taught to be used to regulate target gene sequences *in trans* as taught by Applicants specification and provided in the claimed invention. Rather, Zhou’s array probes are used to directly identify its counterpart gene or mRNA for example, to identify new gene family members (column 17, lines 22-32), characterize genotype knockouts (column 17, lines 8-21), to compare between species (column 16, lines 54-65), analyze genetic selection under selective conditions (column 15, line 38 to column 16, line 6) and study gene expression patterns (see Examples). Zhou’s definition of its mRNA probes provide no definition for miRNAs and rather only focus on the RNA serving as a template for translation (see column 6, line 56 to column 7, line 9). The antisense RNA of Zhou is defined as a probe that is identical in sequence to a gene mRNA sequence that is sought to be identified or studies (column 12, lines 1-9). Nowhere in Zhou is there a teaching or suggesting that the probe sequences of SEQ ID NOS: 1-982,914 are miR related nucleic acids that regulate target genes in trans. One of skill would lack the motivation to identify the claimed nucleic acids from Zhou’s large pool based upon Zhou’s teaching away that any of these sequences are related to miR related sequences.

In addition, over a 1000 different probe sequences either comprise SEQ ID NO: 669995 or are fragments of SEQ ID NO: 669995. Considering the massize size of the genus of sequences taught by Zhou with SEQ ID NO: 669995 alone (i.e., monomer sequences 1 to 1000 of SEQ ID NO: 669995), there is simply no way one of skill would envisage the claimed subgenus of claimed nucleic acids within the genus. Furthermore, one of skill would not be led by the teachings of Zhou and SEQ ID NO: 669995 to select a primer that is related to a miRNA, or any other sequence capable of regulating a gene transcript *in trans*, as provided in claims 23 or use a probe to identify such sequences as in claim 39. Accordingly, the Examiner has failed to provide a *prima facie* case of obvious using the reference Zhou. In view of the foregoing remarks, Applicant submits that the

rejection of claims 23 and 39 under 35 U.S.C. §103(a) over Zhou has been overcome and should be withdrawn.

### **3. Conclusion**

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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